

Application No. 10/526,285  
Amendment dated October 13, 2006  
Response to Office Action dated June 16, 2006

This listing of claims will replace all prior versions, and listing, of claims in the application.

**Listing of Claims:**

1. **(Currently Amended)** A pharmaceutical composition comprising metaxalone in a pharmaceutically acceptable solubility-improved form and at least one pharmaceutically acceptable excipient, characterized in that the pharmaceutical composition has enhanced oral bioavailability as compared to the ~~conventional~~ pharmaceutical composition of metaxalone ~~available commercially corresponding to New Drug Application No. 13-217 when they are~~ administered ~~without feed to a patient who has fasted~~ on an empty stomach
2. **(Cancelled)**
3. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is micronized metaxalone.
4. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is a salt form of metaxalone.
5. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is a crystalline form of metaxalone.
6. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is amorphous metaxalone.
7. **(Original)** A pharmaceutical composition as claimed in claim 1, wherein the composition comprises a mixture of metaxalone and a solubilizing agent.
8. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value between 10 and 40µm in diameter, characterised in that the pharmaceutical composition has enhanced oral bioavailability.

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9. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone has specific surface area per unit volume of more than  $1.5\text{m}^2/\text{cm}^3$ .

10. **(Previously Presented)** A pharmaceutical composition as claimed in claim 9, wherein the metaxalone has specific surface area per unit volume of more than  $2.5\text{m}^2/\text{cm}^3$ .

11. **(Previously Presented)** A pharmaceutical composition as claimed in claim 10, wherein the metaxalone has specific surface area per unit volume of more than  $3.0\text{m}^2/\text{cm}^3$ .

12. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value of  $40\mu\text{m}$ , 90% undersize value of  $30\mu\text{m}$ , and 50% undersize value of  $10\mu\text{m}$ .

13. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value of  $30\mu\text{m}$ , 90% undersize value of  $14\mu\text{m}$ , and 50% undersize value of  $6\mu\text{m}$ .

14. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value of  $10\mu\text{m}$ , 90% undersize value of  $5\mu\text{m}$ , and 50% undersize value of  $3\mu\text{m}$ .

15. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the amount of metaxalone is in the range of 400mg to 1600mg.

16. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the pharmaceutically acceptable excipient comprises a wetting agent.

17. **(Previously Presented)** A pharmaceutical composition as claimed in claim 16, wherein the wetting agent comprises a surfactant.

18. **(Previously Presented)** A pharmaceutical composition as claimed in claim 17, wherein the surfactant comprises sodium lauryl sulfate.

19 – 22      **(Cancelled)**

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23. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative, biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.

24. **(Cancelled)**

25. **(Cancelled)**

26. **(Cancelled)**

27. **(Previously Presented)** A pharmaceutical composition comprising metaxalone and at least one pharmaceutically acceptable excipient, wherein at least 99% of the metaxalone has a particle size not more than about 10 $\mu$ m in diameter.

28. **(Cancelled)**